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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/990,628	11/13/2001	Ronald L. Ream	112703-203	4209

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EXAMINER
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HOWARD, SHARON LEE

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 05/19/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/990,628

Applicant(s)

REAM ET AL.

Examiner

Sharon L. Howard

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 13 February 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 9-26 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 9-26 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4,5.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

Applicant's election without traverse of Group II, claims 9-26 in Paper No. 8 is acknowledged.

Claims 9-26 are pending.

#### **DETAILED ACTION**

Claims 9,10,12,18,19,21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 9 and 18, the word "including" is indefinite because it is not established that there is a specific requirement that the coating comprises a medicament or that it is only exemplary. It is suggested that applicant remove the word "including" and insert the word "comprising".

In claims 10,12,19 and 21, the words "chosen from the group consisting of" is indefinite since it is improper Markush language. Proper Markush language is "selected from the group consisting of".

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 9-11,14,17-20,24 are rejected under 35 U.S.C. 102(b) as being anticipated by Niazi et al. (U.S. Patent No. 4,639,368).

Niazi teaches a chewing gum composition comprising a gum base and a medicament (see abstract, col.2, lines 20-22) capable of being absorbed through the buccal cavity. Niazi teaches that the composition may also contain sweeteners such as aspartame (col. 2, lines 57-68, bridging col.3, line 1) or sugar alcohols. Niazi teaches that the sweetener may range from about 40 weight percent to about 70 weight percent of the total weight of the final gum product (col. 3, lines 8-11). Niazi teaches a taste masking agent (col.4, lines 62-68, col.5, lines 1-15) for masking the unpleasant taste of the medicament. Niazi teaches medicaments such as analgesics, laxatives, antacids, vitamin B12 and trace mineral supplements, local antibiotics (col.4, lines 14-52). Niazi teaches a chewing gum composition containing a gum base, medicaments, corn syrup, sorbitol and a sweetener in the amount of 0.5 grams (see Example 2, Table II at col.6).

The prior art meets the limitations of the claims.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 9-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Niazi et al. (U.S. Patent No. 4,639,368).

Niazi is applied as above.

Niazi does not teach the particular amounts of a sweetener and a taste masking agent.

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Absence of evidence to the contrary, there are no unexpected results, since it would have been obvious to one of ordinary skill in the art at the time the invention was made to determine the suitable amounts of a sweetener and a taste masking agent by routine experimentation.

The expected result would be a chewing gum composition comprising a gum base, a medicament, a sweetener and a taste masking agent.

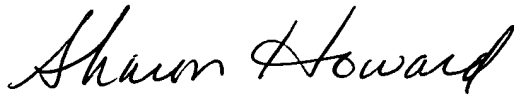
It would have been within the skill of the ordinary practitioner at the time the invention was made to use the teachings of the Niazi reference, because the Niazi reference teaches a chewing gum composition comprising a gum base, a medicament, a sweetening agent and a taste masking agent, which is useful for the purpose of providing absorption of a medicament to the buccal cavity. One would expect similar results.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon L. Howard whose telephone number is (703) 308-4359. The examiner can normally be reached on 9:00am - 5:00pm.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (703) 308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 746-3121 for regular communications and (703) 305-3592 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.



Sharon Howard  
May 10, 2003



THURMAN K. PAGE  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600